

KO30647  
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**Special 510(k) Summary  
for  
EVA Digital Dental Imaging System**

MAR 20 2003

**1. SPONSOR**

AFP Imaging Corporation  
250 Clearbrook Road  
Elmsford, NY 10523

Contact Person: David Vozick  
Telephone: (914) 592-6100

Date Prepared: February 27, 2003

**2. DEVICE NAME**

Proprietary Name: EVA Digital Dental X-Ray System  
Common/Usual Name: Accessory to Extraoral X-Ray System  
Classification Name: Extraoral Source X-Ray System Accessory

**3. PREDICATE DEVICES**

AFP Imaging Sens-A-ray System

**4. INTENDED USE**

The EVA Digital Dental Imaging System is intended to be used with standard digital dental X-ray systems and computer stations for system operation, archive data storage, input capture and enhancement, and patient data and support.

**5. DEVICE DESCRIPTION**

The EVA System (previously named the Sens-A-Ray System) has been modified to incorporate a new sensor component and docking station. The proposed EVA System is essentially identical in intended use and fundamental technology to the parent Sens-A-Ray System described in K923067. The modifications are limited to changing the sensor from a CCD Sensor to a Complimentary Metal Oxide Semiconductor (CMOS) sensor and adding a docking station. As with the original Sens-A-Ray Sensor, the CMOS sensor when exposed to radiation captures the image in the form of a charge pattern on its surface. The resulting

electronic output signals are digitized by a processor and sent to a computer screen for image presentation. The EVA System Sensor and supporting electronics are identical in intended use and fundamental technology to the parent Sens-A-Ray Sensor and supporting electronics.

#### **6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE**

The modified EVA System and the predicate Sens-A-Ray System both include the ProImage application software package. Both systems allow images to be captured, digitized, and uploaded to a standard computer. Both systems consist of an X-ray sensitive solid state imaging array enclosed in a capsule connected via cable to digitizing and control electronics which in turn interface to a computer via a standard interface. The only differences between the predicate and the proposed systems is the EVA system uses a CMOS imager chip in place of the CCD sensor as used in the predicate Sens-A-Ray and the docking station in place of the Imager and Image Grabber. The CMOS Sensor achieves a larger image area with higher resolution and lower power requirements. The EVA's computer hardware interface replaces the obsolete ISA interface used in the Sens-A-Ray with a standard USB interface. The Docking Station includes the commonly used USB interface instead of the ISB for communication between the sensor and the cable.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 20 2003

AFP Imaging  
% Ms. Mary McNamara-Cullinane, RAC  
Staff Consultant  
Medical Device Consultants, Inc.  
49 Plain Street  
NORTH ATTLEBORO MA 02760

Re: K030647  
Trade/Device Name: EVA Digital Dental  
Imaging System  
Regulation Number: 21 CFR 872.1800  
Regulation Name: Extraoral source  
x-ray system  
Regulatory Class: II  
Product Code: 90 EHD  
Dated: February 27, 2003  
Received: February 28, 2003

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030647

Device Name: EVA Digital Dental Imaging System

Indications for Use:

The EVA Digital Dental Imaging System is intended to be used with standard digital dental X-ray systems and computer stations for system operation, archive data storage, input capture and enhancement, and patient data and support.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brugdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K030647

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_